AF/GAU 1644

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By Denise M. Squiresi (print name) (signature)

#15
12/7/98

LUD 5253.5 DIV-JEL/NDH (085911)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Thierry BOON-FALLEUR et al.
Serial No.	:	08/819,669
Filed	:	March 17, 1997
For	:	TUMOR, REJECTION, ANTIGEN PRECURSORS, TUMOR REJECTION ANTIGENS AND USES THEREOF
Art Unit	:	1644
Examiner	:	T. Cunningham

Hon. Commissioner of Patents
and Trademarks
BOX AF
Washington, D.C. 20231

November 30, 1998

RESPONSE TO FINAL REJECTION (37 C.F.R. § 1.116)

SIR:

This is in response to the final rejection, dated September 1, 1998. Claims 173-176 and 179-181 are presented. None have been allowed.

The final rejection maintained rejection 4A, and withdrew rejections 4B, 4C, 4D, 5 and 6. There is a new matter rejection presented therein as well. It is applicants' understanding that the only issues pending are rejection 4A, on pages 2-3, and the rejection set forth over pages 4-5 of the action. Both issues are addressed herein.

In rejection 4A, the examiner asks, "Is this (i.e., 'composition') limited to noncovalently associated ingredients, such as an isolated MAGE-1 antigen and an excipient such as PBS or normal saline?" The answer to this question is NO. Broad language is used, and broad scope is intended.

Claim 179 reads as follows:

> "Composition comprising the isolated tumor rejection antigen precursor of claim 173, and a pharmaceutically appropriate ingredient."

There is no recitation as to "covalent" or "non-covalent" association, and no such limitation was intended. Both are encompassed by the claims.

The examiner goes on to state in 4A:

> "Is this term intended to embrace fusion proteins or protein conjugates comprising the MAGE-1 antigen, e.g., MAGE-1 conjugated to a protein carrier such as KLH or diphtheria toxoid."

It is believed that this question was addressed previously. The examiner did not present the clearer exposition of the issues requested on page 3 of the previous response, so applicants' remarks stand.

The examiner goes on to ask: "Is the term 'composition of matter' intended to have different scope or meaning than the term 'composition' as conventionally used in biotechnology claim language?" Since "of matter" was deleted, this point is moot.

Applicants now turn to the objection brought up at points 7 and 8. Before addressing these points, however, applicants draw the examiner's attention to the following statement, made in the office action of March 17, 1998, at page 5, last 3 lines:

> "If any originally disclosed MAGE-1 amino acid sequence has been modified or corrected the Applicant is requested to notify the examiner of the correction and date the correction was made."

This is a clear indication that the examiner was concerned about correct sequences. It is true that SEQ ID NOS: 7 and 8 are nucleotide sequences; however, they are encoding nucleotide sequences. Note, for example, claim 175.

> The isolated tumor rejection antigen precursor of claim 174, consisting of the amino acid sequence encoded by exons of the nucleotide sequence set forth by SEQ ID NO: 8.

Also note claim 176:

> The isolated tumor rejection antigen precursor of claim 174, wherein said human rejection antigen precursor is encoded by a nucleic acid molecule, the complementary sequence of which hybridizes to SEQ ID NO: 8 under stringent conditions.

SEQ ID NOS: 7 and 8, as was explained in the papers submitted previously, correspond to specific clones described in the application as filed. Please refer to the declaration signed by the inventors and submitted in the prior response, in joint 3 et seq. References made to Examples 20 and 21 of the specification. A specific clone will have a specific sequence. Further, the nucleotide sequence of the clone will be inherent to that clone, in the same way that molecular weight is inherent to a given molecule.

It is not seen how correction of an application to reflect a correct inherent property of a molecule constitutes new matter. If applicants presented the molecular weight of H_2O as 15

kilodaltons, surely there would be no issue in correcting the specification to refer to proper molecular weight. The example given herein parallels the situations with the sequences.

It is also brought to the examiner's attention that in patent application serial no. 07/807,043 which issued as U.S. Patent No. 5,342,774, a reissue application was filed, is pending, and the changes were accepted as NOT constituting new matter.

The examiner states, apparently, that the fact that correct sequences were filed in Genbank in 1993 is irrelevant because the claims "are described in terms of proteins encoded by the sequence of SEQ ID No: 8, not be (sic: by) reference to particular clones decided by deposit number." With all due respect, the information which was provided to Genbank had to come from specific molecules. They are the same molecules under consideration in Examples 20 and 21. Whether a clone is sequenced in the a patent application, Genbank, a scientific journal, etc., the fact remains that a clone has a sequence. Nothing could be clearer. Applicants are reciting an inherent property. This does not constitute new matter.

In point 8,the examiner rejects all claims as lacking adequate description and enablement for the MAGE-1 sequence of SEQ ID NO:8 as amended. The examiner goes on to argue that the instant claims are not directed to the two specific nucleic acid sequences of SEQ ID NOS: 7 and 8 that may have inherently been in possession at the time of filing. This is true; however, it is equally true that the instant claims are directed to the protein or amino acid sequences which these sequences encode. These proteins are inherent to the inherent nucleic acid molecules. The nucleic acid molecules described in examples 20 and 21 encode proteins. The specific clones described therein encode proteins. These clones have an inherent nucleotide sequence. That is

the change that is being made. This does not, and cannot constitute new matter, especially in view of the decision on reissue, referred to supra.

All issues have been addressed. It is believed that this application is now in condition for allowance, and a holding to that end is urged.

Respectfully submitted,

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